

Original Article



# Comparative Analysis on the Efficacy of Monopolar Radiofrequency With Continuous Water Cooling and Conventional Cryogen Spray Cooling in Facial Rejuvenation

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## ABSTRACT

**Background:** Monopolar radiofrequency (MRF) is widely used for non-invasive facial rejuvenation.

**Objective:** In this study, we compared the clinical efficacy and patient-reported procedural pain of a novel MRF system with continuous water cooling (RF-CWC) versus conventional MRF with cryogen spray cooling (RF-CSC) in 22 Asian women.

**Methods:** In this prospective, randomized, split-face, single-blind trial, 22 participants received a single session of both RF-CWC and RF-CSC. Clinical outcomes—including changes in pore size, elasticity, skin density, fine lines, and lifting—were assessed over 8 weeks using quantitative measurements and investigator-assessed global improvement scores. Procedural pain was also recorded. To support the clinical findings, an *ex vivo* model was used to evaluate collagen and elastin fiber density, collagen I and III concentrations, and dermal temperature profiles.

**Results:** RF-CWC demonstrated clinical efficacy comparable to that of RF-CSC in terms of lifting, skin volume, and wrinkle reduction, while significantly reducing procedural pain. *Ex vivo* analysis confirmed enhanced collagen remodeling and efficient dermal heating with RF-CWC.

**Conclusion:** RF-CWC offers a clinically effective and better-tolerated alternative to traditional cryogen-cooled MRF for facial rejuvenation.

**Trial Registration:** Clinical Research Information Service Identifier: [KCT0010406](https://www.kctri.re.kr/ctri/ctriViewDetail.do?ctriId=KCT0010406)

**Keywords:** Radiofrequency therapy; Rejuvenation; Skin aging

## INTRODUCTION

Treatments for skin laxity and elasticity loss have traditionally involved interventions such as surgical procedures and chemical peels, which are often associated with lengthy recovery times

and potential complications<sup>1-3</sup>. This challenge has propelled the exploration of anti-aging treatments leveraging energy-based technologies such as lasers, radiofrequency (RF), and ultrasound since the early 2000s<sup>4-6</sup>. Among these, monopolar radiofrequency (MRF) has emerged as a pivotal advancement, recognized for its

effectiveness in reducing facial wrinkles by delivering targeted thermal energy to the dermis. The Food and Drug Administration first approved an MRF device for facial wrinkle reduction in 2002<sup>4</sup>.

The efficacy of MRF depends on its precision in delivering an effective amount of thermal energy to the dermis while sparing the epidermis from damage. Traditionally, MRF treatments have utilized cryogen spray cooling (CSC) to lower epidermal temperature, requiring the treatment to be applied in a static mode<sup>4,5,7,10</sup>. This static application can cause thermal injury if the handpiece loses complete contact with the skin, resulting in inconsistent energy distribution. Although rapid cooling methods minimize epidermal heat damage, they can also compromise the warming effect essential for stimulating the papillary dermis, as contact cryogen cooling may also reduce papillary dermal temperature<sup>11</sup>.

Continuous water cooling (CWC) technology has been designed to protect the epidermis from thermal harm while achieving relatively uniform thermal effects throughout the dermis, from the superficial papillary layer to the deeper reticular dermis. In contrast to the traditional spray cooling method, which requires the handpiece to be in static contact with the epidermis<sup>4,5,7,10</sup>, this novel cooling method allows for the handpiece to be freely moved during treatment, facilitating consistent cooling and dynamic application.

The objective of this study was to evaluate whether monopolar radiofrequency treatment using continuous water cooling (RF-CWC) is non-inferior in terms of clinical efficacy to conventional monopolar radiofrequency with cryogen spray cooling (RF-CSC) while offering improved tolerability in terms of procedural pain. We hypothesized that RF-CWC would demonstrate rejuvenation outcomes comparable or superior to those of RF-CSC, with reduced patient discomfort. A split-face randomized design was used to enable intra-individual comparison, thereby minimizing inter-subject variability. This approach provides a comprehensive evaluation of the therapeutic potential of this novel RF-CWC device in the context of non-invasive facial rejuvenation.

## MATERIALS AND METHODS

### Clinical study design and patient selection

This prospective, randomized, split-face, single-blinded clinical trial took place at Severance Hospital (Seoul, Korea). Eligible participants were female, aged 38 to 50 years old. The primary objective of the trial was to determine whether the novel RF-CWC device demonstrated non-inferior clinical efficacy compared to that of the conventional RF-CSC system<sup>11</sup>. The sample size was based on previous non-inferiority trials of monopolar RF systems and deemed sufficient to detect clinically meaningful

differences with 80% power at a 2-sided significance level of 0.05. The split-face design allowed for within-subject comparison, enhancing statistical efficiency.

The exclusion criteria were as follows: 1) pregnancy, breastfeeding, or non-adherence to contraception protocols; 2) active lesions at the treatment site that could interfere with assessment; 3) known allergies or hypersensitivity reactions; 4) irritation resulting from cosmetics, medications, or ultraviolet exposure; 5) history of skincare treatments or procedures within the past 3 months; and 6) use of identical or similar topical agents or medications at the treatment site within 3 months prior to study initiation.

The study protocol adhered to the ethical principles outlined in the Declaration of Helsinki, and written informed consent was obtained from all participants prior to enrollment. This study was approved by the Institutional Review Board (IRB) of Severance Hospital, Yonsei University (IRB No. YUHS IRB-4-2022-0993, GIRB-23601-PH), and the study was registered with the Clinical Research Information Service under the identifier KCT0010406.

### Treatment protocol

We compared the clinical efficacy and procedural pain associated with RF-CWC (Volnewmer; CLASSYS, Seoul, Korea) and RF-CSC (Thermage FLX; Thermage, Bothell, WA, USA), ensuring equivalent power density across devices. RF-CWC was administered in a dynamic “moving mode,” while RF-CSC was applied in the conventional static mode. Prior to the treatment, both cheeks of participants were applied an equal amount of topical anesthesia. Participants then received split-face treatment, with 300 shots of each device delivered to opposing cheeks at a fixed power level of 2.5. To ensure comparability between the 2 systems, the experiments were standardized by controlling the output power at 65 watts, resulting in a delivered energy of approximately 65 joules per shot for both devices. All procedures were conducted consistently under these conditions. Participants were randomly assigned using a computer-generated sequence to Group A (right cheek first) or Group B (left cheek first), with device allocation alternating based on whether the number of the individual participant was odd or even. This randomization ensured balanced and unbiased distribution of treatments between facial sides.

Objective clinical outcomes—including changes in skin density, pore size, elasticity, fine lines, lifting, and volume—were assessed using standardized imaging and measurement tools. In addition, 3 independent, blinded dermatologists evaluated overall improvement using a 7-point Global Improvement Scale (GIS), and participants rated procedural pain using a 10-point visual analog scale. The protocol reflects standard clinical practice reported in previous studies<sup>12,13</sup>.

The primary objective of the trial was to determine whether the novel RF-CWC device demonstrated non-inferior clinical

efficacy compared to that of the conventional RF-CSC system. The sample size of 22 participants was determined based on precedent established by Wang et al.<sup>11</sup>, who evaluated non-inferiority between 2 monopolar RF devices in a parallel-arm design with 20 subjects per group. Adopting a split-face design allowed for within-subject comparisons, thereby reducing inter-individual variability and enhancing statistical power. This design, in combination with the paired structure, was considered sufficient to detect clinically meaningful differences in primary efficacy endpoints while maintaining 80% power at a 2-sided significance level of 0.05.

### Efficacy evaluations

Lifting of the cheek and perioral skin was measured using F-RAY (BEYOUNG Co., Seoul, Korea). Skin volume was assessed using Morpheus 3D (Morpheus Co., Seongnam, Korea). Perioral fine lines were evaluated using PRIMOS Lite (Phaseshift Rapid In-vivo Measurement Of Skin; Canfield Scientific, Parsippany, NJ, USA). Skin pores were measured using Antera 3D CS (Miravex, Dublin, Ireland). Skin elasticity was measured using Cutometer Dual MPA 580 (Courage + Khazaka Electronic GmbH, Köln, Germany). Skin density was determined using Skin Scanner (tpm GmbH, Schüttorf, Germany), and high-resolution photography was conducted using Visia-CR (Canfield Scientific). Lastly, the GIS was measured by 3 blinded, independent dermatologists based on a 7-point scale (1, very much better; 7, very much worse) (**Supplementary Fig. 1**). To ensure inter-rater reliability in the GIS assessments, the investigators underwent a detailed training session to standardize their evaluation criteria, using a set of standardized photographs to align their ratings.

### Safety and adverse reaction

During each visit to the dermatology department, the patients underwent a thorough physical examination to evaluate the safety of the procedure, with detailed documentation of adverse events such as burns, bruising, scarring, and atrophy post laser treatment. Procedural pain was assessed using a 10-point scale at the end of each split-face treatment session, enabling patients to rate their discomfort level (10 indicating severe pain, 1 indicating no pain). Subjective pain scores were compared between the 2 split-face devices at 100, 200, and 300 shot intervals, with patients providing ratings on the same 10-point scale during each assessment.

### Ex vivo skin model preparation and RF-CWC treatment

Human abdominal skin tissue obtained for research purposes (IRB No. GIRB-23601-PH) was prepared by removing the subcutaneous adipose layer and washing repeatedly

with phosphate-buffered saline to eliminate residual debris. The cleaned tissue was cut into uniform 10 cm × 5 cm sections and subjected to UV-B irradiation at 312 nm (300 mJ/cm<sup>2</sup>/day) using a UV cross-linker (BLX 312; Vilber Lourmat, Collégien, France) to induce photoaging.

Following UV-B exposure, each tissue sample was treated with 12 shots of monopolar RF-CWC at an energy level of 2.5 (16.25 J/cm<sup>2</sup>). Treatment groups were defined by the interval time between each shot: 25 seconds, 12 seconds, or 1 second. The 25 seconds interval was chosen to simulate realistic clinical conditions, reflecting the approximate return time to the same facial area during actual split-face treatment with 300 shots over 75 cm<sup>2</sup>. The 12 seconds and 1 second intervals were included to assess the thermal and biological effects of shot stacking under shorter cooling intervals. Additional groups included a non-irradiated untreated control and a UV-B-only group without RF application.

After treatment, all tissue samples were cultured for 72 hours in an incubator set at 37°C with a 5% CO<sub>2</sub> atmosphere using a semi-solid medium comprising Dulbecco's modified Eagle's medium (Hyclone, Logan, UT, USA) supplemented with 10% fetal bovine serum (Gibco, Grand Island NY, USA) and 1% penicillin-streptomycin (Gibco) before histological staining and biochemical analysis.

### Histological analysis

Following the 72 hours incubation, tissues were fixed in 10% formalin and embedded in paraffin. Sections of 5 µm thickness were obtained and stained using Masson's trichrome and Verhoeff-Van Gieson protocols to evaluate collagen and elastic fiber architecture. Stained slides were imaged with an optical microscope (BX43F; Olympus, Tokyo, Japan) and quantified using the Zen image analysis software (Carl Zeiss AG, Oberkochen, Germany). The collagen and elastin content within the papillary dermis was expressed as a percentage relative to total tissue area.

### Quantitative protein assay (enzyme-linked immunosorbent assay [ELISA])

Additional tissue samples harvested after 72 hours were homogenized using a TissueLyser II (Qiagen, Venlo, Netherlands), followed by centrifugation (2,000× g, 10 minutes). Protein concentration was determined using bicinchoninic acid (BCA) assay (Sigma-Aldrich, St. Louis, MO, USA). Collagen types I and III were quantified using commercial ELISA kits (Collagen I: Abcam, Cambridge, UK; Collagen III: Biocompare, South San Francisco, CA, USA), according to the manufacturers' protocols. Absorbance was measured using a microplate reader (VARIOSCAN LUX; Thermo Fisher Scientific, Waltham, MA, USA), and concentrations were calculated via standard curve regression.

### Ex vivo dermal temperature profiling

To evaluate the thermal penetration behavior of the novel RF-CWC system under standardized and reproducible conditions, an *ex vivo* skin model was employed. Human abdominal skin tissue was processed to remove the subcutaneous adipose layer and cut into 5 cm × 10 cm sections. A thermocouple K-type probe (Teflon®-coated; Chemours, Wilmington, DE, USA) connected to a digital thermometer (OMEGA Engineering, Norwalk, CT, USA) was inserted at the mid-dermal level of each sample to capture subsurface temperature in real time. A return pad was positioned 2 cm away from the treatment zone to prevent local heat accumulation. RF energy was applied at levels 2.5 and 4.0 using the RF-CWC device. Temperature data were recorded at 1 second intervals using OM-HL Logpro software (OMEGA Engineering), allowing continuous thermal mapping throughout the treatment session.

### Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, NY, USA). Normality of continuous variables was assessed using the Shapiro–Wilk test. For within-group comparisons across time points, repeated-measures analysis of variance was applied for normally distributed data, while the Friedman test was used for non-parametric data. Between-group comparisons were conducted using paired-samples t-tests or Wilcoxon signed-rank tests, depending on data distribution. A 2-sided *p*-value of <0.05 was considered statistically significant.

## RESULTS

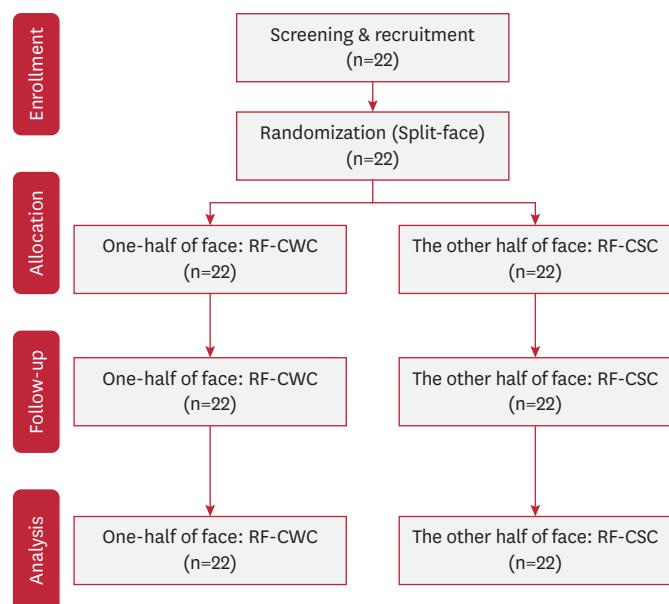
### Recruitment and epidemiological characteristics of participants

Our eligible cohort included 22 healthy female participants with a mean age of 46±3 years, and all participants successfully completed the study without dropping out. The process of recruitment, allocation, and follow-up, which took place from June 19, 2023–August 25, 2023, is depicted in **Fig. 1**.

### Comparison of clinical efficacy between RF-CWC and RF-CSC

#### 1) Enhanced skin density, elasticity, and pore refinement; fine-line smoothening; and increased facial lifting and volume

Both RF-CWC and RF-CSC groups demonstrated significant improvements in skin density and pore size post-treatment. Changes in skin density at 2, 4, and 8 weeks were consistently higher in the RF-CWC than in the RF-CSC group (RF-CWC - 2 weeks, 6.351%; RF-CSC - 2 weeks, 5.83%; RF-CWC - 4 weeks, 9.762%; RF-CSC - 4 weeks, 8.921%; RF-CWC - 8 weeks, 8.297%;



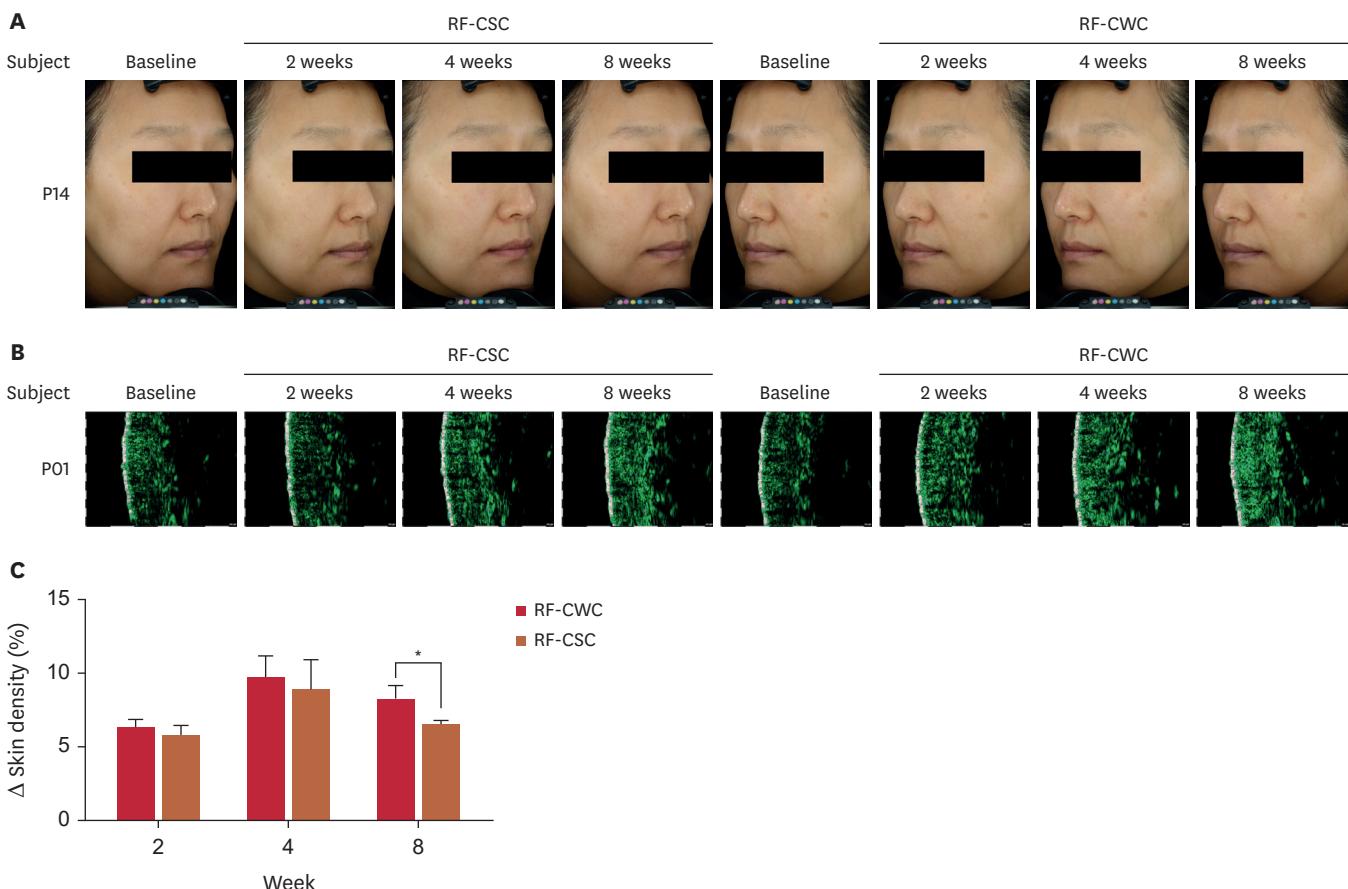
**Fig. 1.** Flowchart of the procedure used to recruit, screen, and randomize the participants.

RF-CWC: monopolar radiofrequency system with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling.

RF-CSC - 8 weeks, 6.565%; **Fig. 2**). Notably, the improvement at 8 weeks was significantly greater with RF-CWC (**Fig. 2C**; *p*<0.05 by paired t-test).

Moreover, the reduction in pore size was greater in the RF-CWC group than in the RF-CSC group at all-time points (2, 4 and 8 weeks) (RF-CWC - 2 weeks, -8.732 mm<sup>2</sup>; RF-CSC - 2 weeks, -3.059 mm<sup>2</sup>; RF-CWC - 4 weeks, -11.636 mm<sup>2</sup>; RF-CSC - 4 weeks, -6.232 mm<sup>2</sup>; RF-CWC - 8 weeks, -15.422 mm<sup>2</sup>; RF-CSC - 8 weeks, -9.169 mm<sup>2</sup>; **Fig. 3A and B**; *p*<0.05 by Wilcoxon signed-rank test). Skin elasticity increased over time in both groups. At 2, 4, and 8 weeks, *R*<sup>2</sup> values improved with a similar trend, and no significant differences were noted between the 2 procedures (RF-CWC - 2 weeks, 0.056; RF-CSC - 2 weeks, 0.056; RF-CWC - 4 weeks, 0.088; RF-CSC - 4 weeks, 0.087; RF-CWC - 8 weeks, 0.109; RF-CSC - 8 weeks, 0.113; **Fig. 3C**).

Both RF modalities led to significant improvements in perioral fine lines (**Fig. 3D**). No significant between-group differences were observed in Ra (average roughness), implying comparable effects on overall surface roughness (RF-CWC - 2 weeks, -1.083; RF-CSC - 2 weeks, -0.814; RF-CWC - 4 weeks, -1.886; RF-CSC - 4 weeks, -1.483; RF-CWC - 8 weeks, -2.493; RF-CSC - 8 weeks, -2.549; **Fig. 3E**). The RF-CWC group showed significantly greater reduction in Rmax (maximum roughness depth) at 4 and 8 weeks (RF-CWC - 2 weeks, -10.612; RF-CSC - 2 weeks, -5.952; RF-CWC - 4 weeks, -20.121; RF-CSC - 4 weeks, -11.8; RF-CWC - 8 weeks, -28.543; RF-CSC - 8 weeks, -18.372; **Fig. 3E**; *p*<0.05 at 4 and 8 weeks by Wilcoxon signed-rank test), possibly indicating



**Fig. 2.** Comparative improvements in skin density after RF-CWC and RF-CSC. (A) Visia-CR images of the patients at baseline and 2, 4, and 8 weeks post-treatments. (B) Skin Scanner analysis revealing improvements in skin density after monopolar radiofrequency treatments. (C) Skin density following the RF-CWC procedure shows a significant increase compared to that after the RF-CSC procedure.

RF-CWC: monopolar radiofrequency with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling.

\*p<0.05 by paired-samples t-test.

superior improvement in deeper wrinkles. For the Rt parameter (total height of roughness), the 4-week measurement demonstrated a significant difference favoring RF-CWC, suggesting earlier dermal remodeling activity (RF-CWC - 2 weeks, -10.233; RF-CSC - 2 weeks, -7.045; RF-CWC - 4 weeks, -21.396; RF-CSC - 4 weeks, -12.306; RF-CWC - 8 weeks, -30.187; RF-CSC - 8 weeks, -20.542; **Fig. 3E**; p<0.05 at 4 weeks by Wilcoxon signed-rank test).

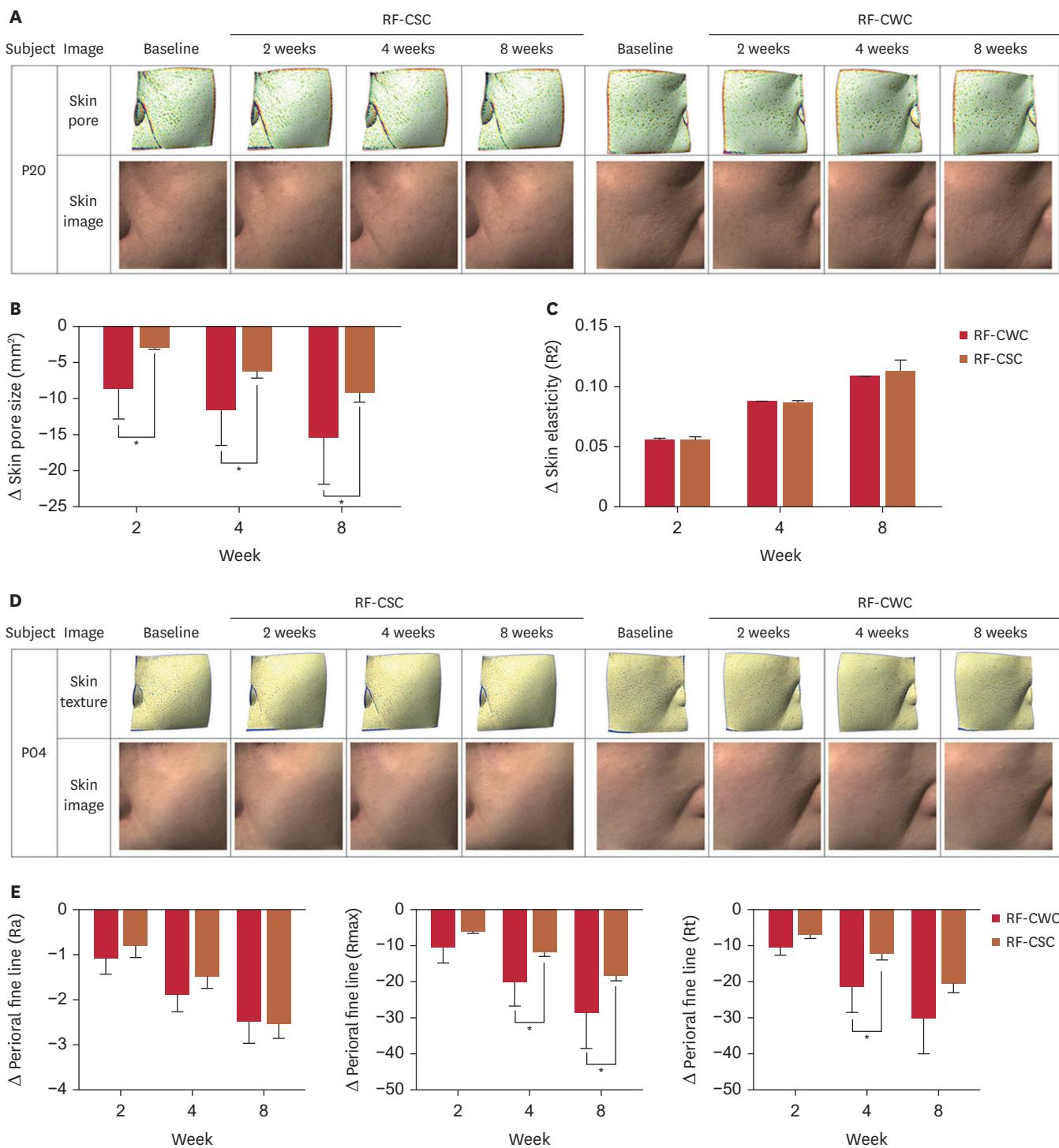
Facial lifting and volumetric enhancement were evaluated at baseline and 2, 4, and 8 weeks post-treatment using F-RAY and Morpheus 3D, respectively. Cheek and perioral lifting were quantified using the F-RAY imaging system, which measures angular displacement of facial landmarks. Changes were expressed in degrees (°), with larger angles indicating greater lifting effects. Both RF-CWC and RF-CSC treatments led to progressive improvements in cheek lifting angles over time, with no significant differences observed between groups at any time point (RF-CWC - 2 weeks, 0.813°; RF-CSC - 2 weeks, 0.864°; RF-CWC - 4 weeks, 1.420°; RF-CSC - 4 weeks, 1.572°; RF-CWC - 8 weeks, 2.066°;

RF-CSC - 8 weeks, 2.332°; **Fig. 3F**). Perioral lifting angles also increased similarly in both groups, demonstrating comparable lifting effects across all follow-up visits (RF-CWC - 2 weeks, 0.743°; RF-CSC - 2 weeks, 0.656°; RF-CWC - 4 weeks, 1.574°; RF-CSC - 4 weeks, 1.517°; RF-CWC - 8 weeks, 2.348°; RF-CSC - 8 weeks, 2.236°; **Fig. 3F**).

Skin volume increased gradually in both groups through to week 8. Although numerical trends varied slightly at each time point, no significant differences were noted between RF-CWC and RF-CSC in terms of volumetric improvement (RF-CWC - 2 weeks, 9.359 ml; RF-CSC - 2 weeks, 12.199 ml; RF-CWC - 4 weeks, 16.436 ml; RF-CSC - 4 weeks, 13.945 ml; RF-CWC - 8 weeks, 18.387 ml; RF-CSC - 8 weeks, 20.345 ml; **Fig. 3G**). These findings suggest that both devices demonstrated equivalent efficacy in enhancing facial lifting and volume.

## 2) Investigator-assessed clinical improvement of wrinkles

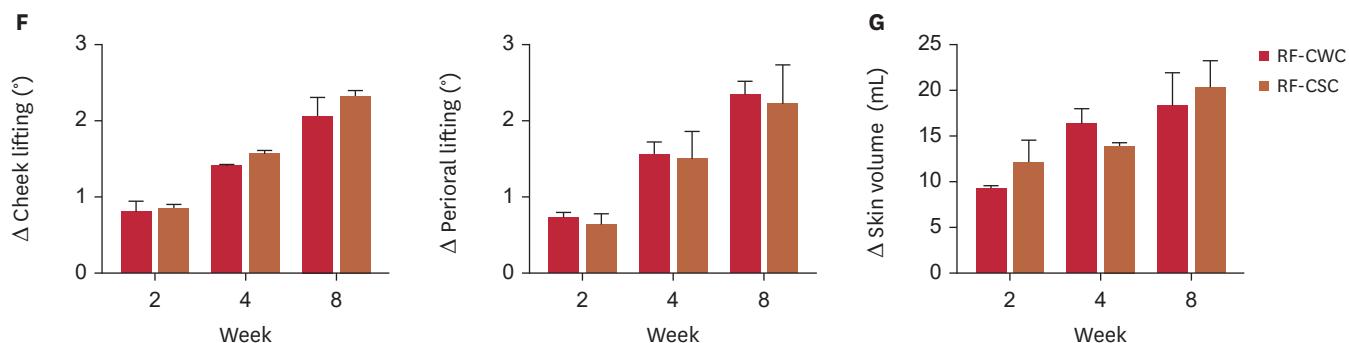
Both RF-CWC and RF-CSC demonstrated comparable levels of



**Fig. 3.** Improvements in skin characteristics after RF-CWC and RF-CSC treatments. (A) Antera 3D images at baseline and 2, 4, and 8 weeks after MRF treatments. (B) Quantitative comparison of changes in skin pore size after MRF treatments. (C) Improvement in skin elasticity after RF-CWC and RF-CSC treatments. (D) Antera 3D images of skin texture at baseline and 2, 4, and 8 weeks after MRF treatments. (E) Changes in perioral fine lines (Ra, Rmax, Rt) after MRF treatments. (F) Quantitative comparison of cheek lifting and perioral skin lifting after MRF treatments. (G) Changes in skin volume after MRF treatments. RF-CWC: monopolar radiofrequency with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling, MRF: monopolar radiofrequency, Ra: average roughness, Rmax: maximum roughness, Rt: total height of roughness.

\*p<0.05 by Wilcoxon signed-rank test.

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**Fig. 3.** (Continued) Improvements in skin characteristics after RF-CWC and RF-CSC treatments. (A) Antera 3D images at baseline and 2, 4, and 8 weeks after MRF treatments. (B) Quantitative comparison of changes in skin pore size after MRF treatments. (C) Improvement in skin elasticity after RF-CWC and RF-CSC treatments. (D) Antera 3D images of skin texture at baseline and 2, 4, and 8 weeks after MRF treatments. (E) Changes in perioral fine lines (Ra, Rmax, Rt) after MRF treatments. (F) Quantitative comparison of cheek lifting and perioral skin lifting after MRF treatments. (G) Changes in skin volume after MRF treatments. RF-CWC: monopolar radiofrequency with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling, MRF: monopolar radiofrequency, Ra: average roughness, Rmax: maximum roughness, Rt: total height of roughness.

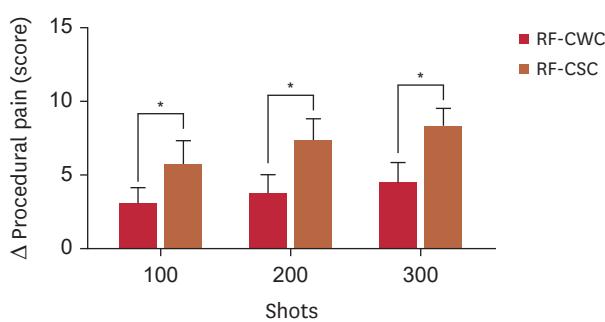
\* $p<0.05$  by Wilcoxon signed-rank test.

improvement, with no significant differences observed between the 2 treatments (**Supplementary Fig. 1**).

### Safety profile and procedural pain

Follow-up examinations conducted immediately after the procedure and at 2, 4, and 8 weeks revealed no significant adverse effects. Mild post-treatment redness and edema were transient and resolved spontaneously. No persistent erythema or swelling was observed in any participant throughout the study period, supporting the safety of both devices.

Procedural pain, assessed on a 10-point scale, was significantly lower with RF-CWC than with RF-CSC at all measured time points (RF-CWC - 100 shots,  $3.114\pm1.046$ ; RF-CSC - 100 shots,  $5.795\pm1.563$ ; RF-CWC - 200 shots,  $3.818\pm1.230$ ; RF-CSC - 200 shots,  $7.432\pm1.425$ ; RF-CWC - 300 shots,  $4.545\pm1.327$ ; RF-CSC - 300 shots,  $8.386\pm1.174$ ; **Fig. 4**;  $p<0.05$  by Wilcoxon signed rank test), highlighting the enhanced tolerability and comfort associated with RF-CWC treatment.



**Fig. 4.** Comparative evaluation of procedural pain via a 10-point scale. RF-CWC: monopolar radiofrequency with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling.

\* $p<0.05$  by Wilcoxon signed-rank test.

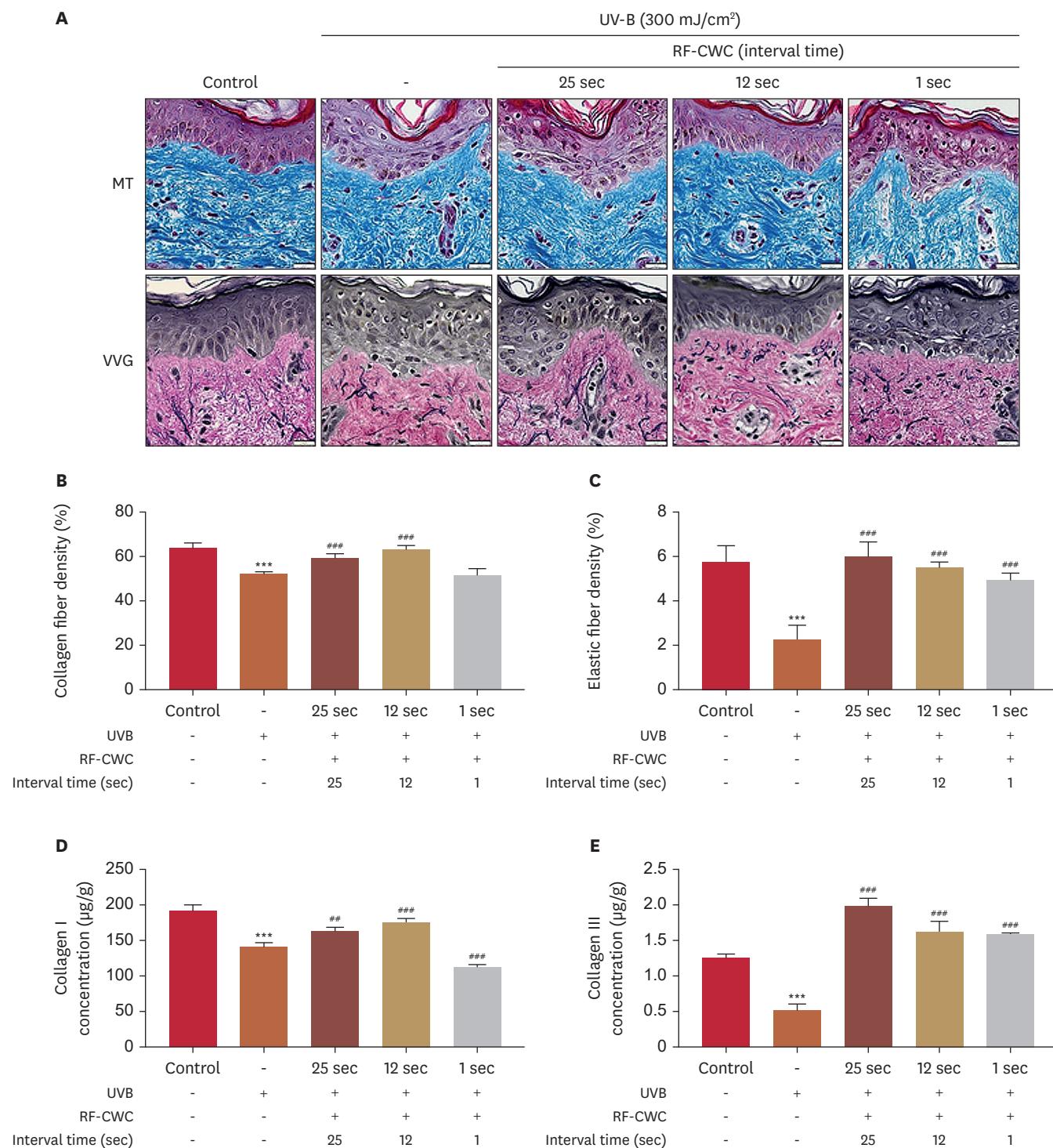
### Ex vivo analysis

Collagen fiber density was markedly reduced following UV-B irradiation compared to that in the control group. RF-CWC treatment restored collagen density in an interval-dependent manner, with the 12 and 25 seconds groups showing notable recovery, while the 1 seconds group exhibited minimal improvement, comparable to UV-B-irradiated samples without treatment (**Fig. 5A and B**;  $p<0.005$ ). This suggests that sufficient time between shots is essential for promoting collagen reorganization without thermally inducing damage.

Elastin fiber density showed a similar pattern. UV-B exposure led to a sharp reduction in elastin content, which was partially reversed by RF-CWC treatment (**Fig. 5C**;  $p<0.005$ ). Restoration was the most prominent in the 25 seconds group, followed by the 12 seconds group. By contrast, the 1 second group showed limited recovery, again underscoring the importance of controlled energy delivery timing for optimal dermal remodeling.

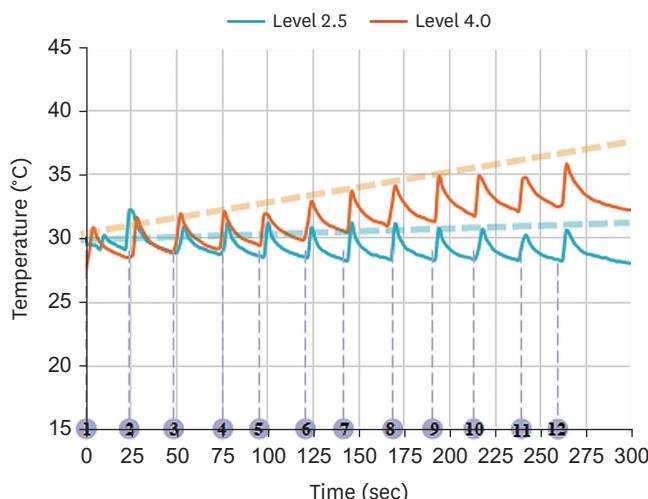
Quantification of collagen I protein levels further supported these findings. UV-B exposure significantly decreased collagen I concentration, whereas RF-CWC treatment at 12 and 25 seconds intervals substantially enhanced its production (**Fig. 5D**;  $p<0.005$ ). By contrast, the 1 second interval group exhibited still lower collagen I levels than the UV-B-only group, suggesting that insufficient recovery time may suppress collagen synthesis owing to cumulative thermal stress.

Finally, analysis of collagen III concentration showed that RF-CWC treatment effectively counteracted UV-B-induced suppression in a manner consistent with the interval-dependent trends observed in other biomarkers. Both the 25 and 12 seconds groups showed meaningful restoration of collagen III, while the 1 second group failed to reach comparable levels (**Fig. 5E**;  $p<0.005$ ). Collectively, these findings suggest that RF-CWC effectively promotes extracellular matrix remodeling by stimulating



**Fig. 5.** Comparative results in a UV-B-exposed skin aged model ex vivo study after RF-CWC and monopolar radiofrequency with cryogen spray cooling. (A) Alterations in collagen fiber density and elastic fiber density of the UV-B-exposed ex vivo model after MRF treatments. (B) Collagen fiber density of the control, UV-B-exposed, and treatment groups (25 seconds, 12 seconds, and 1 second interval between MRF shots). (C) Comparative analysis of elastic fiber density. (D) Collagen I concentration and (E) Collagen III concentration via enzyme-linked immunosorbent assay. All experiments were repeated at least 3 times. UV-B: ultraviolet B, RF-CWC: monopolar radiofrequency with continuous water cooling, MRF: monopolar radiofrequency, MT: Masson's Trichome, VVG: Verhoeff-Van Gieson.

\*\*\*p<0.005 compared with control; \*\*p<0.01 compared with UV-B irradiation; \*\*\*p<0.005 compared with UV-B irradiation.



**Fig. 6.** Monopolar radiofrequency with continuous water cooling irradiation at levels 2.5 (16.25 J/cm<sup>2</sup>) and 4.0 (23.75 J/cm<sup>2</sup>) produced a rapid, transient rise in dermal temperature followed by a prompt return to baseline between shots in an *ex vivo* human skin model.

dermal fibroblasts when sufficient intervals between shots are maintained, thereby minimizing thermal overload and enhancing regenerative signaling in photoaged tissue.

#### Dermal temperature dynamics in *ex vivo* skin

Thermal dynamics were assessed using an *ex vivo* human skin model to characterize dermal heating behavior and evaluate the effectiveness of the cooling mechanism in RF-CWC at clinically relevant energy levels (16.25 J/cm<sup>2</sup> [level 2.5] and 23.75 J/cm<sup>2</sup> [level 4.0]). To accurately capture temporal temperature changes, 12 shots were delivered at 25 seconds intervals, allowing sufficient time for thermal stabilization between exposures. RF-CWC treatment resulted in controlled and reproducible dermal heating, with each shot generating a consistent peak temperature followed by a rapid return to baseline. At level 2.5, dermal temperature increased to approximately 31°C and returned to approximately 28.6°C between shots. At level 4.0, peak temperatures remained below 34°C, with recovery at an average of 30.5°C. These findings confirm the effectiveness of CWC in preventing excessive thermal accumulation while maintaining safe and consistent energy delivery to the dermis (Fig. 6).

## DISCUSSION

Previous studies have reported that MRF improves skin firmness and appearance by promoting collagen contraction and stimulating neocollagenesis, resulting in facial rejuvenation<sup>14-16</sup>. Traditional treatments for skin laxity, such as surgery or chemical peels, are often associated with extended downtime and higher

risks of complications. By contrast, newer RF modalities aim to enhance clinical outcomes with greater patient comfort. Our study provides a comprehensive comparison between the novel RF-CWC and conventional RF-CSC systems, demonstrating that RF-CWC yields comparable improvements in facial aesthetics—including improvements in skin density, pore size, elasticity, fine wrinkles, lifting, and facial volume—while significantly reducing procedural discomfort.

These results align with previous findings from studies on conventional MRF systems that demonstrated that sub-ablative dermal heating (i.e., heating below the threshold of tissue necrosis) can trigger fibroblast activation and extracellular matrix remodeling<sup>4,13,17</sup>. However, RF-CWC distinguishes itself from earlier technologies through the incorporation of CWC and dynamic handpiece mobility. This design not only enhances treatment uniformity but also minimizes the risk of heat-related epidermal damage. In comparison, traditional RF-CSC systems rely on static application and rapid CSC, which may create uneven thermal distribution and limit consistent dermal penetration.

The therapeutic mechanism of MRF is strongly dependent on temperature-specific interactions with dermal tissue, ranging from reversible fibroblast stimulation at 42°C–45°C to thermal coagulation at 57°C–61°C<sup>17,19</sup>. Achieving optimal thermal exposure without damaging the epidermis is therefore critical for maximizing neocollagenesis. The RF-CWC system was developed to address this challenge, offering dynamic energy delivery that allows continuous movement across the skin surface while maintaining thermal control. This innovation facilitates even heat diffusion across dermal layers, contributing to both treatment safety and efficacy.

Emerging theoretical frameworks, such as the application of fractal geometry to cutaneous anatomy, support the need for a thermal gradient that extends across the full thickness of the skin—from the epidermis to the reticular dermis and even to the superficial subcutis<sup>20-23</sup>. Rather than rapidly cooling superficial layers alone, RF-CWC enables a more physiological temperature gradient through its CWC mechanism. This was evidenced in our *ex vivo* thermal analysis, where RF-CWC demonstrated consistent subsurface temperature peaks followed by gradual cooling between shots. Such temperature dynamics suggest that RF-CWC minimizes epidermal heat accumulation while promoting sustained dermal activation, contributing to reduced procedural pain and enhanced neocollagenesis.

The papillary dermis, rich in type III collagen, is particularly important in wound healing and regeneration<sup>24,25</sup>. Our results suggest that RF-CWC effectively stimulates both superficial and deep dermal fibroblasts by delivering controlled thermal energy throughout the dermis. This dual-layer activation involving both the papillary and reticular dermis may account for the clinical

improvements observed not only in lifting and volume but also in pore size and fine wrinkles. *Ex vivo* analysis further demonstrated increased dermal thickness and elastic fiber density, along with significant upregulation of collagen types I and III. These molecular changes reinforce the observed clinical outcomes and highlight the potential of RF-CWC as a comprehensive skin rejuvenation tool.

Nonetheless, this study has several limitations. The sample size was relatively small and consisted exclusively of Asian female participants, which may limit generalizability of the findings. Long-term efficacy was not assessed, whereas earlier studies have shown that conventional MRF maintains improvements for up to 6 months<sup>10,13,26,27</sup>. Moreover, our *ex vivo* evaluation focused solely on RF-CWC; a direct comparison with RF-CSC in an identical model would provide further insight into their respective biological effects.

In conclusion, our findings suggest that RF-CWC significantly reduces procedural discomfort while achieving facial rejuvenation outcomes that are comparable to those attained by RF-CSC. The combination of dynamic energy delivery and continuous cooling appears to offer an optimal balance between safety and efficacy. Future research should include large-scale, multi-ethnic trials with extended follow-up periods to validate these outcomes and refine treatment protocols for broader clinical use.

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The authors have nothing to disclose.

#### DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## SUPPLEMENTARY MATERIAL

### Supplementary Fig. 1

Comparison of visual evaluation using a 7-point global improvement score. GIS: global improvement score, RF-CWC: monopolar radiofrequency with continuous water cooling, RF-CSC: monopolar radiofrequency with cryogen spray cooling.

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